DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 31 2010

Re: Vimpat
NDA 22-253
Patent Nos. 5,654,301 and RE38,551
Docket Nos.: FDA-2009-E-0172
FDA-2009-E-0174

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 5,654,301 and RE38,551, filed by Research Corporation Technologies, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for Vimpat (lacosamide), the human drug product claimed by the patents.

The total length of the regulatory review period for Vimpat (lacosamide) is 3,452 days. Of this time, 3,055 days occurred during the testing phase and 397 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 19, 1999.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 19, 1999.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: September 28, 2007.

   FDA has verified the applicant's claim that the new drug application (NDA 22-253) for Vimpat tablets was submitted on September 28, 2007.

3. The date the application was approved: October 28, 2008.

   FDA has verified the applicant's claim that NDA 22-253 was approved on October 28, 2008.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Kevin G. Shaw
Hogan & Hartson, LLP
555 Thirteenth Street, NW
Washington, DC 20004